

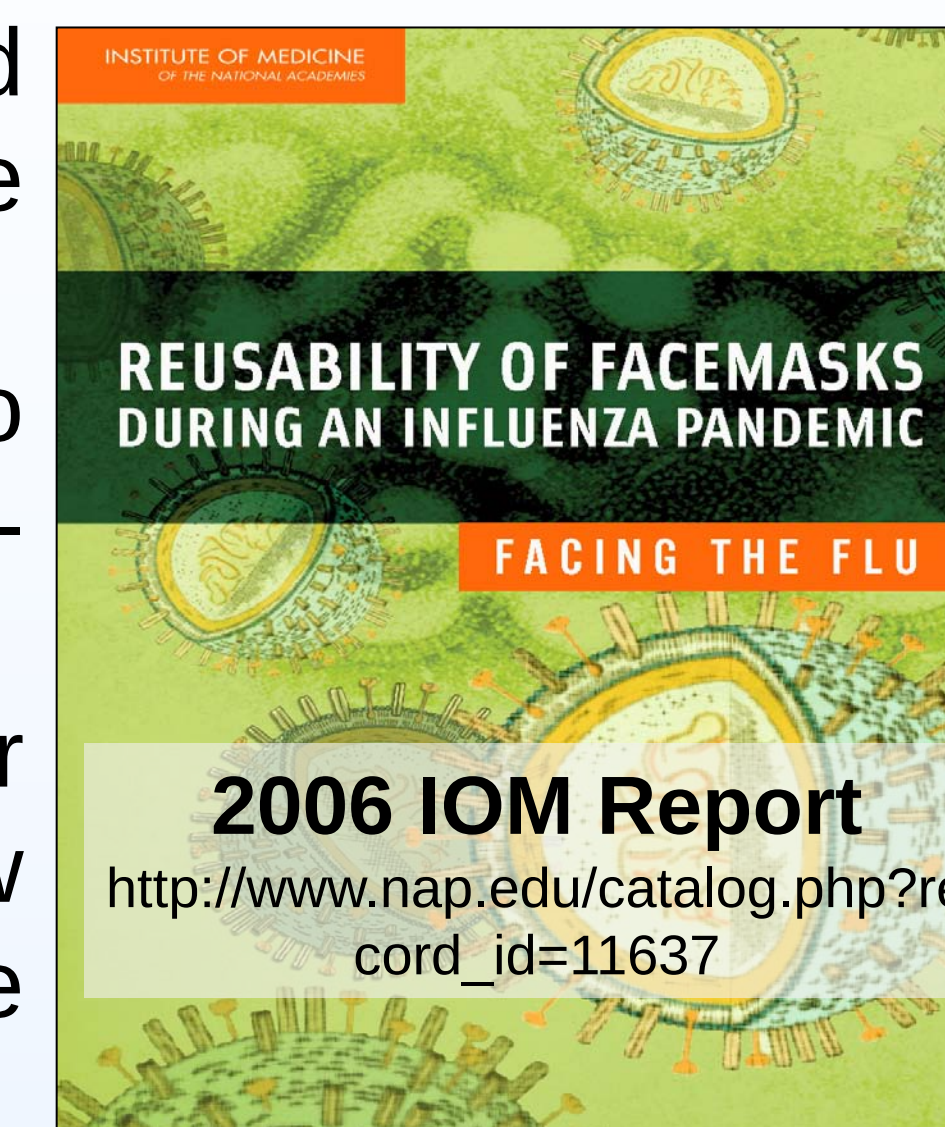
Reusability of Filtering Facepiece Respirators

Evanly Vo¹, Michael S. Bergman², Edward M. Fisher¹, Debra A. Novak¹, Samy Rengasamy¹, Dennis J. Viscusi¹, and Ronald E. Shaffer¹

¹NIOSH/NPPTL, Pittsburgh, PA, ²URS Corp., Pittsburgh, PA

Background

- During a pandemic, there will be an increased reliance on disposable N95 filtering facepiece respirators (FFRs).
- Greater than 90 million N95 FFRs will be needed to protect workers in the healthcare sector during a 42-day outbreak. A respirator shortage is possible.
- The use of decontamination methods to render trapped infectious material inactive and allow respirator reuse has been suggested as a possible strategy to overcome a respirator shortage.
- The Institute of Medicine (IOM) recommended studies on the effect of simple decontamination methods on respirator performance. NPPTL initiated research in 2006 to address IOM recommendations.



NPPTL Research Project

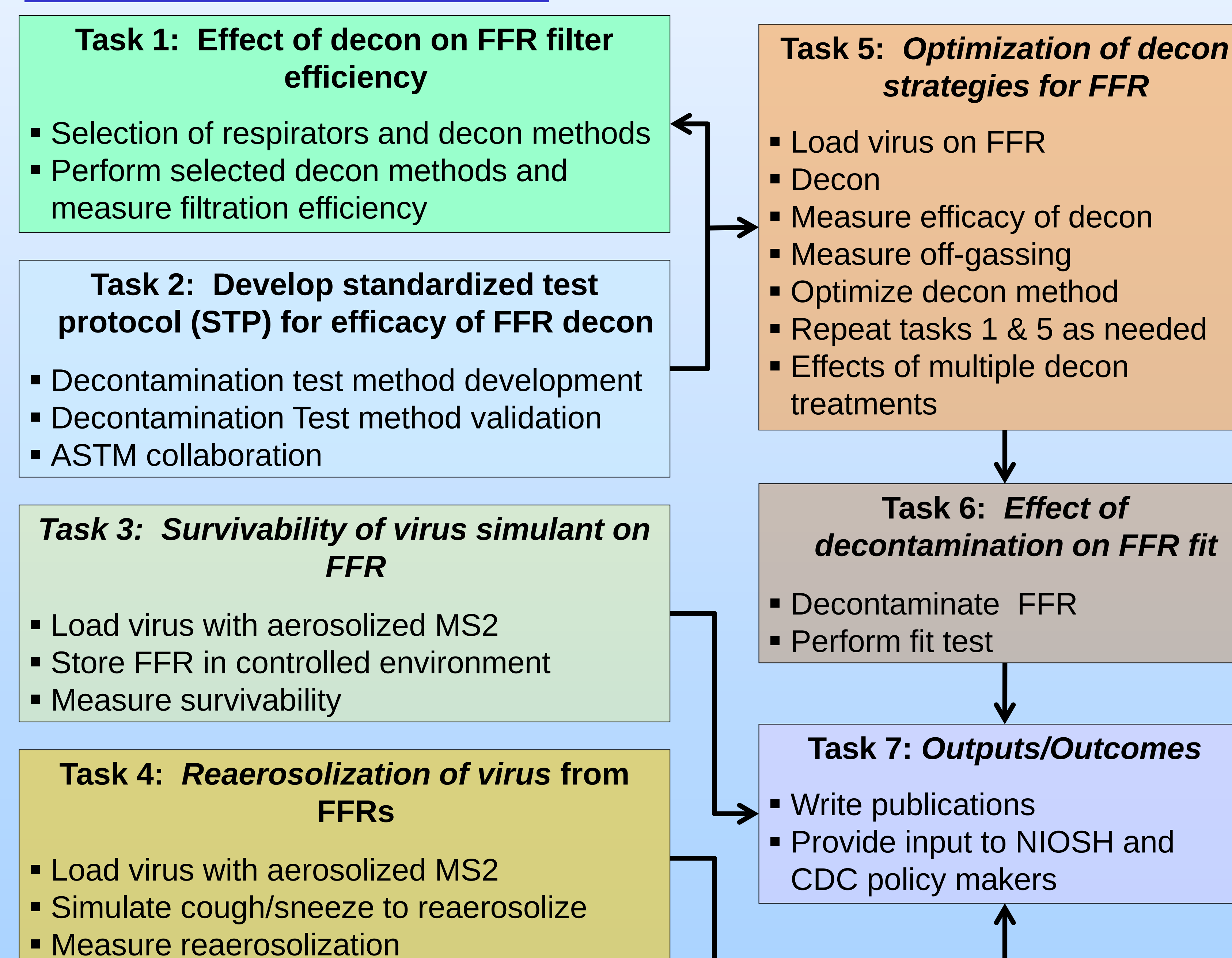


Figure 1. Overview of NPPTL Reusability of FFR Research Project

Stakeholders

- Healthcare Workers & Administrators
- Infection Control
- Respirator Manufacturers
- Standards Development Organizations (e.g., ASTM)

Partners

- Technical Support Working Group (TSWG)
- Air Force Research Laboratory (AFRL)
- Food and Drug Administration
- University of Florida
- University of Nebraska Medical Center

Project Status and Preliminary Findings

Task 1: Effect of decontamination on FFR filter efficiency

- Autoclave, 160°C dry heat, 70% isopropyl alcohol, and soap & water caused significant filter and/or physical degradation, while the effects of most other decontamination methods were found to be model specific.
- Although bleach and dry microwave treated FFRs exhibited expected levels of filtration performance, other effects such as odor/off-gassing (bleach) and melting (microwave) were problematic.
- UVGI, microwave generated steam (MGS), and moist heat (MH, 60°C, 80% RH, <4 hours) are considered to be the most promising methods for possible FFR decontamination and will be used for future studies.

Task 2: STPs for Measuring the Efficacy of FFR decontamination

- Developed methods to apply virus (Coliphage MS2) to FFR samples and coupons as wet particles (droplets) and dry particles (droplet nuclei).
- Characterized the devices and validated decontamination efficacy using chemical (bleach) and physical (steam, UVGI) methods.

Task 3: Survivability of virus simulant on FFR

- Tests conducted at 22°C and 30% RH demonstrated a 2.3 log(10) reduction in viable MS2 with 10 days of storage.
- FFR with integrated antimicrobial technology demonstrated no antiviral effect stored for 20 hrs at 22°C and 30% RH.

Task 4: Reaerosolization of virus from FFR

- Less than 1% of viable virus loaded onto the respirator were reaerosolized by the simulated cough.
- Fine aerosols of MS2 loaded onto the FFR were more susceptible to reaerosolization than viruses loaded as larger droplets (>10 µm).
- Particles were reaerosolized following the 1st cough. Samples collected following the 2nd or 3rd coughs resulted in non-detections.

Task 5: Optimization of decontamination strategies for FFR

- UV-C penetration into the FFR generally decreased with an increase in protein or organic/inorganic residues (protective factors).
- MS2 inactivation was a function of model-specific UV-C doses to the internal filtering medium; decontamination efficacy was model-specific.
- Efficacy of MGS decontamination was not affected by the level of protective factors.

Task 6: Effect of decontamination on FFR fit

- Two FFRs demonstrated a small increase in smell and two different FFRs demonstrated a statistically significant reduction in fit after MH decontamination; however, average fit factors were still passing (• • • • •).
- Respirator users with characteristics similar to those in this study population are unlikely to experience a large reduction in fit, increase in smell and discomfort, or increased difficulty in donning with these FFR models after UV-C, MGS, or MH decontamination.

Task 7: Outputs/Outcomes (To Date):

Outputs

Task 1:

- Viscusi et al. Effect of Decontamination on the Filtration Efficiency of Two FFR Models. *J. Int. Soc. Resp. Prot.*, (2007) 24: 93-107.
- Viscusi et al. Evaluation of the filtration performance of 21 N95 FFRs after prolonged storage. *Am. J. Infect. Control*, (2009) 37:381-386.
- Viscusi et al. Evaluation of Five Decontamination Methods for FFRs. *Ann. Occup. Hyg.*, (2009) 53: 815-827.

Task 2:

- Fisher et al. Development of a test system to evaluate procedures for decontamination of respirators containing viral droplets. *Appl. Environ. Microbiol.*, (2009) 75: 1500-1507.
- Vo et al. Development of a Test System to Apply Virus Containing Particles to FFRs for the Evaluation of Decontamination Procedures. *Appl. Environ. Microbiol.*, (2009) 75: 7303-7309.

Task 3:

- Rengasamy et al. Evaluation of the survivability of MS2 viral aerosols deposited on FFR samples incorporating antimicrobial technologies. *Am. J. Infect. Control*, (2010) 38: 9-17.

Task 4:

- Richardson et al. Final Report for Reaerosolization of Viruses from NIOSH-Certified Filtering Facepiece Respirators. May 2008.

Outcomes

- ASTM test methods were developed for viral decontamination of air-permeable materials (e.g., FFRs) using a droplet method (work item# 19888) and a droplet nuclei method (work item# 19887). The draft ASTM standard methods are available at:
<http://www.astm.org/DATABASE.CART/WORKITEMS/WK19887.htm>
<http://www.astm.org/DATABASE.CART/WORKITEMS/WK19888.htm>

TSWG Funded Collaboration – Relevant Findings

- AFRL evaluated decontamination protocols using H1N1 influenza A.
- UV-C, MGS, and MH provide > 3-log reduction of viable H1N1 virus.
- H1N1 virus was reduced to non-detectable amounts in 92.6% of the FFRs evaluated.

Summary and Future Work

- Decontamination of FFRs for purpose of reuse is currently not recommended, although preliminary data is promising.
- Future work will investigate decontamination of other types of respirators and additional experiments to better assess the risks of handling contaminated respirators.

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